

## REMARKS

Entry of the foregoing and reconsideration of the application identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.111 and in light of the remarks which follow, are respectfully requested.

Applicants and Applicants' representative thank Examiner Azpuru of the U.S. Patent and Trademark Office for his time and consideration in participating in an interview with Applicants' representative on September 17, 2009. During the interview, a proposed amendment to claim 14 was discussed, and the Examiner advised that he would reconsider the application upon submission of a written response amending such claim in the proposed manner.

By the above amendments, claim 21 has been canceled without prejudice or disclaimer. The subject matter of canceled claim 21 has been incorporated into independent claim 14. Claim 14 has also been amended to delete the recitation that the polymer is in a hardened state. Claim 22 has been amended to depend from claim 14 in view of the cancellation of claim 21.

In the Official Action, claims 14-43, 64 and 65 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Without addressing the propriety of the Examiner's comments in connection with this rejection, and in an effort to expedite prosecution, the recitation that the polymer is in a hardened state has been deleted from claim 14. Accordingly, withdrawal of the above rejection is respectfully requested.

Claims 14-20, 23, 32, 33 and 38-43 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 4,645,503 (*Lin et al*) in view of U.S. Patent Application Publication No. US 2002/0016636 (*Ricci et al*). Claim 31 stands rejected

under 35 U.S.C. §103(a) as being obvious over *Lin et al* in view of *Ricci et al*, and further in view of U.S. Patent No. 4,610,692 (*Eitenmuller et al*). Claims 14-20, 23-25, 28, 30, 32-34 and 38-43 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,869,445 (*Johnson*) in view of *Lin et al* and further in view of *Ricci et al*. Claims 26 and 27 stand rejected under 35 U.S.C. §103(a) as being obvious over *Johnson* in view of *Lin et al* and further in view of *Ricci et al* and further in view of U.S. Patent No. 6,455,024 (*Glajch et al*). Claim 29 stands rejected under 35 U.S.C. §103(a) as being obvious over *Johnson* in view of *Lin et al* and further in view of *Ricci et al* and further in view of *Glajch et al*, and further in view of U.S. Patent No. 5,338,772 (*Bauer et al*). Claim 31 stands rejected under 35 U.S.C. §103(a) as being obvious over *Johnson* in view of *Lin et al* and further in view of *Ricci et al* and further in view of *Eitenmuller et al*. Claims 35-37 stand rejected under 35 U.S.C. §103(a) as being obvious over *Johnson* in view of *Lin et al* and further in view of *Ricci et al* and further in view of U.S. Patent No. 3,918,968 (*Kukla et al*).

As noted above, the subject matter of claim 21 has been incorporated into independent claim 14. Claim 21 has not been included in any of the above rejections. Accordingly, the above rejections are moot in view of the above amendment to claim 14, and as such, withdrawal of the rejections is respectfully requested.

Claims 21, 22, 24, 25 and 28 stand rejected under 35 U.S.C. §103(a) as being obvious over *Lin et al* in view of *Ricci et al*, and further in view of *Bauer et al*. As noted above, claim 14 has been amended to incorporate the subject matter of claim 21. For at least the following reasons, Applicants submit that independent claim 14 is non-obvious over the above applied documents.

Independent claim 14 is directed to a biocompatible and biodegradable implant for filling a cavity in a living organism comprising polymer-coated biocompatible and biodegradable granules fused together through polymer linkage. As noted above, the subject matter of claim 21 has been incorporated into claim 14. As such, claim 14 now recites that the polymer linkage is carried out such that after fusing the granules together, an open interconnected porosity with macropores having an average diameter in a range of about 100  $\mu\text{m}$  to about 500  $\mu\text{m}$ , is achieved.

*Lin et al* (taken in view of *Ricci et al*) does not disclose or suggest each feature recited in independent claim 14. For example, *Lin et al* does not disclose or suggest that polymer linkage is carried out such that after fusing the granules together, an open interconnected porosity with macropores having an average diameter in a range of about 100  $\mu\text{m}$  to about 500  $\mu\text{m}$ , is achieved. This deficiency of *Lin et al* has been acknowledged by the Patent Office at page 8 of the Official Action dated October 31, 2008.

*Bauer et al* fails to cure the above-described deficiencies of *Lin et al*. In this regard, the Patent Office has relied on *Bauer et al* for disclosing a bone implant having macropores with sizes in the range of 0.01 - 1 mm. See Official Action dated October 31, 2008, at page 8. However, Applicants submit that it would not have been obvious to the ordinarily skilled artisan, upon fair and complete consideration of the *Bauer et al* and *Lin et al* disclosures, to modify *Lin et al* by employing the macroporous structure disclosed by *Bauer et al*.

In this regard, *Bauer et al* discloses an implant material, in which calcium phosphate ceramic particles are joined to one another by polymer bridges to give a three-dimensional, open-pore structure. *Bauer et al* discloses that in the open-pore

structure, the particle surfaces are covered with polymer to the extent of not more than 50%. See col. 3, lines 13-21. In obtaining the open-pore structure, *Bauer et al* emphasizes the criticality of employing such partial particle coverage of not more than 50%:

With a proportion of ceramic particles of at least 50% by weight and the joint which develops via polymer bridges, it is ensured that the particle surfaces are covered with polymer to the extent of not more than 50%. [Col. 3, lines 38-42.]

A decisive feature of the composite material according to the invention is the three-dimensionally open-pore structure, which is constructed such that the calcium phosphate ceramic particles are joined to one another by polymer bridges, the particle surfaces being covered with polymer to the extent of not more than 50%. [Col. 5, lines 19-25.]

The high proportion of exposed surface of the calcium phosphate ceramic particles of at least 50% and preferably 75-95% promotes the preferred regeneration and growth of endogenous mineral bone substance with reduced regeneration of connective tissue. [Col. 7, lines 16-21.]

Clearly, *Bauer et al* teaches the criticality of employing the partial particle coverage of not more than 50%, in obtaining the open-pore structure of the implant.

In stark contrast, *Lin et al* relates to a bone-implant material prepared by mixing filler particles with a flowable biocompatible thermoplastic binder. See col. 3, lines 16-19. *Lin et al* discloses that in the production process, the binder and the filler particles are mixed together and thoroughly blended. See col. 5, line 54 to col. 6, line 4. *Lin et al* teaches that such mixing and thorough blending of the binder and filler particles are effective to achieve adequate void space, good particle cohesiveness and ease in moldability. **Thus, *Lin et al* emphasizes the importance of thorough contact between the binder and filler particles.** It would not have been obvious to the ordinarily skilled artisan to employ the open-pore structure taught by *Bauer et al* in the thoroughly blended binder/particle mixture disclosed by *Lin et al*. The artisan would

have recognized that the partial particle coverage of not more than 50% which is critical to obtaining the open-pore structure of *Bauer et al*, is not appropriate for use in the thoroughly blended binder/particle mixture of *Lin et al*. Further, by emphasizing the importance of thorough contact between the binder and filler particles, *Lin et al* **teaches away** from such proposed modification.

For at least the above reasons, it is apparent that independent claim 14 is non-obvious over the applied art. Accordingly, withdrawal of the above §103(a) rejection is respectfully requested.

Claims 21 and 22 stand rejected under 35 U.S.C. §103(a) as being obvious over *Johnson* in view of *Lin et al*, and further in view of *Ricci et al* and further in view of *Bauer et al*. As noted above, claim 14 has been amended to incorporate the subject matter of claim 21. For at least the following reasons, Applicants submit that independent claim 14 is non-obvious over the above applied documents.

*Johnson* (taken in view of *Lin et al*, and further in view of *Ricci et al*) does not disclose or suggest each feature recited in independent claim 14. For example, *Johnson* does not disclose or suggest that polymer linkage is carried out such that after fusing the granules together, an open interconnected porosity with macropores having an average diameter in a range of about 100  $\mu\text{m}$  to about 500  $\mu\text{m}$ , is achieved. This deficiency of *Johnson* has been acknowledged by the Patent Office at page 14 of the Official Action dated October 31, 2008.

*Bauer et al* fails to cure the above-described deficiencies of *Johnson*. In this regard, the Patent Office has relied on *Bauer et al* for disclosing a bone implant having macropores with sizes in the range of 0.01 - 1 mm. See Official Action dated October 31, 2008, at page 14. However, Applicants submit that it would not have been obvious

to the ordinarily skilled artisan, upon fair and complete consideration of the *Bauer et al* and *Johnson* disclosures, to modify *Johnson* by employing the open-pore structure disclosed by *Bauer et al*.

As discussed above, *Bauer et al* teaches the criticality of employing the partial particle coverage of not more than 50%, in obtaining the open-pore structure of the implant. By comparison, *Johnson* relates to a fabric bag for insertion into an enlarged chamber between vertebrae. *Johnson* discloses placing a tube into an open mouth of the bag, and introducing beads into the bag. The addition of the beads causes the bag to expand into intimate contact with the walls of the chamber. See col. 7, lines 24-33. *Johnson* discloses that the polymer-coated surfaces permit the beads to flow past each other readily as they are poured from one container to another, and the polymer coating protects the beads from breakage and fragmentation during flow as in the filling and packing process. See col. 6, lines 29-33. **Thus, *Johnson* teaches the importance of employing the polymer coating in order to facilitate the flow of the beads and to protect the beads from breakage and fragmentation during flow.**

It would not have been obvious to the ordinarily skilled artisan to modify the coated beads disclosed by *Johnson* to have the open-pore structure taught by *Bauer et al*. As noted above, *Bauer et al* teaches the criticality of employing partial particle coverage of not more than 50%, in obtaining the open-pore structure. In stark contrast, *Johnson* teaches that the coating of its beads has the important functions of permitting bead flow, and providing protection from breakage and fragmentation during flow. In view of such functions of the *Johnson* polymer coating, the ordinarily skilled artisan would not have modified such beads to employ the partial particle coverage of not more than 50% taught by *Bauer et al*, which is critical for obtaining the open-pore structure.

Further, by emphasizing the importance of the polymer coating, *Johnson teaches away* from such proposed modification.

For at least the above reasons, it is apparent that independent claim 14 is non-obvious over the applied documents. Accordingly, withdrawal of the above §103(a) rejection is respectfully requested.

Claim 14 stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 36, 42 and 43 of copending Application No. 10/540,323. This rejection is moot in view of the above amendments, in which the subject matter of claim 21 has been incorporated in claim 14. In this regard, claim 21 has not been included in the above rejection. Accordingly, for at least this reason, withdrawal of the provisional obviousness-type double patenting rejection is respectfully requested.


From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited. If there are any questions concerning this paper or the application in general, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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